DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone: 612-334-4100

93739d

December 12, 2002

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 03 - 09

Edward D. Muir
Member/Owner
Southern Herb Acquisition Co., LLC
1001 Stewart Street
Madison, Wisconsin 53713

Dear Mr. Muir:

This letter is in reference to your firm's marketing and distribution of various products documented by our inspection conducted August 8 and 9, 2002, at your facility located at 1001 Stewart Street, Madison, Wisconsin.

Dr. Christopher's brand Kid-e-Trac is identified in your sales catalog as being intended "For Anxiety, Depression & Hyperactivity." The label for this product states "It has been used as an alternative to drugs for hyperactivity." Your catalog states that Mother Earth Ezzeac with Cat's Claw is intended to be "used by diabetics and those with debilitating diseases such as cancer." These claims evidence that these products are intended for use as drugs as defined in Section 201(g)(1)(B) of the Federal Food, Drug, and Cosmetic Act (the Act). They are also new drugs under Section 201(p) of the Act and may not be legally marketed in the United States without an approved new drug application [Section 505(a) of the Act].

These drugs are also misbranded [Section 502(f)(1) of the Act] because the labeling fails to bear adequate directions for use. In addition, the labeling is false and misleading because it suggests that the products are safe and effective for their intended uses when, in fact, this has not been established [Section 502(a) of the Act].

In reference to the marketing of the product "Miracle II Neutralizer," the promotional material, including your Internet website, www.southernherb.com, from which products may be ordered, indicates that the product is useful in the treatment of various conditions. These include:

- "Aches & Pains"; "Acne Problems"; "AIDS"; "Allergies"; "Alzheimer"; "Arthritis"; "Bed Sores"; "Bronchitis"; "Cancer"; "Candida Albicans"; "Cataracts"; "Chicken Pox"; "Cellulite"; "Colic"; "Crohn's Disease"; "Common Colds"; "Constipation"; "Dermatitis"; "Diabetes"; "Ear Ache"; "Fever Blisters"; "Gulf War Illness"; "Finger Nail Fungus"; "Head Lice"; "Hemorrhoids"; "Herpes, Ulcers"; "Gingivitis"; "Gout"; "High Blood Pressure"; "Lymphoma-Follicular Cancer"; "Lyme Disease & Lupus"; "Mouth Ulcers"; "Parasites"; "Pink Eye"; "Ryder's Syndrome"; "Shingles"; "Skin Cancer and Psoriasis"; "Snake or Spider Bites"; "Sore Throat"; "Stomach Ulcers and Acid Problems"; "Thyroid Problems"; "Tumors"; and "Yeast Infection."

- Promotional material for the product also includes testimonials saying that it can be used to treat extreme backache, chicken pox, arthritis, cataracts, Epstein-Barr, cancer, hemorrhoids, arthritis, torn ligaments, Lyme's disease, and skin cancer.

- The label states that the product is an "an emergency room in a bottle" which implies that the product is intended to treat conditions requiring medical attention.

Based on the evidence of intended use in the product's promotional materials, "Miracle II Neutralizer" is a drug within the meaning of Section 201(g) of the Act because it is intended to be used in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans, or to affect the structure or any function of the body of man. The product's labeling renders the drug a new drug within the meaning of Section 201(p) of the Act because there is no evidence that it is generally recognized as safe and effective for its labeled uses. "Miracle II Neutralizer" may not be legally marketed in the United States since no new drug application (NDA) has been approved for this product, as required by Section 505 of the Act. The product is also misbranded within the meaning of Section 502(f)(1) of the Act because the labeling fails to bear adequate directions for use for the conditions for which it is offered.

Numerous additional products and claims are included in your firm's product catalog. Such claims may also cause these products to be misbranded and/or unapproved new drugs. Examples of these products and claims include:

Quantum Super Lysine + -- "...to effectively fight herpes outbreaks"

Kid-e-Well – "Cold & Flu"

VF Syrup – "Elimination of parasites"

Smoke Out Extract – "A blend of herbs to stop smoking"

Wobenzym N Painful Joint Kit – "...Wobenzyme supports the removal of corrosive proteins that cause inflammation and prevent healing, while glucosamine and chondroitin (Painful Joint Caps) stimulate the rebuilding of cartilage in the damaged joint; packaged in arthritis-friendly, single dose packets."

Nature's Essence ArthroAide – "Herbal Arthritis formula"

This letter is not intended to be an all-inclusive review of labeling and products your firm may market. It is your responsibility to ensure that all products marketed by your firm are in compliance with the Act and its implementing regulations. Labeling is not limited to the immediate product containers but includes all promotional literature which you distribute in connection with your products.

It is noted that you distribute promotional literature provided to you by your suppliers. This literature may also cause the product to be misbranded.

We request that you take prompt action to correct these violations. Failure to promptly correct these violations may result in enforcement action being initiated by the Food and Drug Administration without further notice. The Federal Food, Drug and Cosmetic Act provides for the seizure of illegal products and/or injunction against the manufacturer and/or distributor of illegal products.

Please notify this office in writing within 15 working days of receipt of this letter of the specific steps you have taken to correct the stated violations, including an explanation of each step being taken to identify and make corrections to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be implemented.

Your reply should be sent to the attention of Compliance Officer Tyra S. Wisecup. **After December 23, 2002, correspondence should be mailed to our new District office location at 212 Third Avenue South, Minneapolis, Minnesota 55401.**

Sincerely,

Cheryl A. Bigham
Acting Director
Minneapolis District